PATIENT INFORMATION LEAFLET FOR

GLYGARD

SCHEDULING STATUS: S3

GLYGARD gliclazide 80 mg, tablets

Gliclazide

Contains sugar: Lactose monohydrate 73,5 mg per tablet

Read all of this leaflet carefully before you start taking GLYGARD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- GLYGARD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GLYGARD is and what it is used for
2. What you need to know before you take GLYGARD
3. How to take GLYGARD
4. Possible side effects
5. How to store GLYGARD
6. Contents of the pack and other information.

1. What GLYGARD is and what it is used for

GLYGARD contains gliclazide that belongs to a class of medicine known as sulphonylurea antidiabetic medicine. GLYGARD works by stimulating pancreas to release insulin into blood stream.

GLYGARD is used to treat a certain type of diabetes mellitus called type 2 diabetes in adults, when diet alone does not have an adequate effect on keeping blood sugar at the correct level. When you have type 2 diabetes, the amount of insulin your pancreas produces may not be enough or your body may not be using it properly and you may still need more.

2. What you need to know before you take GLYGARD

Do not take GLYGARD:

- if you are hypersensitive (allergic) to gliclazide, other sulphonylureas (medicine for diabetes) sulphonamides (antibiotic), or any of the other ingredients of GLYGARD (listed in **section 6**).
- if you have insulin-dependent diabetes mellitus (Type I diabetes).
- if you have a liver or kidney disease.
- if you have acid (acidosis) or ketones (diabetic ketoacidosis - a life-threatening problem that occurs when the body cannot use sugar (glucose) as a fuel source because there is no insulin or not enough insulin in your blood).
- If you constantly feel tired, weak, lose weight and mood changes (adrenal or thyroid dysfunction).
- if you are pregnant or breastfeeding your baby.
- if you are a child, as the safety of GLYGARD has not been proven in children.

- If you have an unstable diabetes where blood glucose levels are extremely unstable, leading to frequent and severe fluctuations between high (hyperglycaemia) and low (hypoglycaemia) levels, often causing frequent hospitalizations.
- if you have severe burns or injuries, coma, severe infection, or had a major surgery, resulting in your blood glucose level severely influenced.
- if you are taking a medicine to treat fungal infections called miconazole (see Other medicines with GLYGARD.

Warnings and precautions

Take special care with GLYGARD:

- Before taking GLYGARD you should talk to your doctor. You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, to observe the dietary regimen, have physical exercise and, where necessary, reduce weight.
- During GLYGARD treatment regular monitoring of your blood, (and possibly urine), sugar level and also your glycated haemoglobin is necessary.
- In the initial weeks of treatment, the risk of low blood sugar may increase, and careful monitoring is necessary. Prolonged or serious episodes of hypoglycaemia (low blood sugar), even if controlled by sugar intake, require immediate medical treatment or even hospitalisation.

Low blood sugar (hypoglycaemia) may occur:

- if you are a patient, especially elderly or unable to cooperate
- if you do not eat meals at regular intervals or skip meals altogether
- if you are fasting
- if you are malnourished

- if you change your diet
- if you increase your physical activity and carbohydrate intake does not match this increase
- if you drink a significant amount of alcohol, especially when skipping meals
- if you have any severe abnormal condition of the blood vessels (arteries and veins), including severe heart disease
- if you are taking or have recently stopped taking high doses of corticosteroids (used for pain and inflammation)
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex)
- if your kidney function or liver function is severely decreased
- if you take other medicines or natural remedies at the same time
- if you have taken an overdose of GLYGARD.

If you have low blood sugar you may have the following symptoms:
headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, and helplessness.
The following signs and symptoms may also occur sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self-control, your breathing may be shallow and your heartbeat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, for instance glucose tablets, sugar cubes, sweet juice, sweetened tea. Remember that artificial sweeteners are not effective. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

In order to avoid gastrointestinal side effects (see **Side effects**), you should take your tablets with breakfast.

Should you experience side effects affecting the liver, your doctor may change your medicine.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking GLYGARD.

Symptoms of low blood sugar may be absent, less obvious, or develop very slowly, or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (for instance those acting on the central nervous system and beta blockers).

It is important that you learn which symptoms of low blood sugar you usually have, so that you can treat it quickly. You must also educate your family members about the symptoms of hypoglycaemia and how to treat them.

Symptoms of high blood sugar (hyperglycaemia) may occur when: gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor, if you take St John's wort (*Hypericum perforatum*) preparations, or in special stress situations. If you are in stress situations (accidents, surgical operations, fever etc.), your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

If these symptoms occur, you must contact your healthcare provider or pharmacist.

The effects of GLYGARD may reduce over long periods of time and your doctor may increase your dose and request you increase the frequency of monitoring of your sugar levels.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when GLYGARD is prescribed at the same time as medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you of the importance of monitoring your blood glucose.

There is a potential for the occurrence of serious skin conditions to develop (toxic dermal necrolysis and allergic vasculitis).

Symptoms include a painful, red area that spreads quickly, skin peeling without blistering, raw areas of skin, discomfort, fever, purple-coloured spots and patches on the skin, blisters, hives, open sores).

Your doctor may request tests to monitor your condition before or during treatment.

Children and adolescents

The safety and efficacy of GLYGARD in children has not been established (see **Do not take GLYGARD**).

Other medicines and GLYGARD

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines increase the risk of hypoglycaemia or even coma and should not be used:

- Miconazole and fluconazole (medicines use to treat fungal infection).

The following medicines or substances may cause your blood sugar levels to fall even lower than normal when taken together with GLYGARD and are therefore not recommended for use:

- phenylbutazone (used to treat pain and inflammation)
- alcohol increases the risk of hypoglycaemia (low blood sugar) and coma. Alcohol and medicines containing alcohol should be avoided.

The blood sugar lowering effect of GLYGARD may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken

- allopurinol, probenecid, sulphinpyrazone (anti-gout medicine),
- anabolic steroids (a steroid hormone which promotes muscle growth) and androgens (male sex hormone),
- certain medicines used to treat high blood pressure and heart disease called ACE inhibitors (captopril, enalapril, quinidine, quinine and clonidine), and antidysrhythmics (disopyramide),
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril),
- antibiotics (chloramphenicol, sulphonamides, quinolones, tetracyclines, clarithromycin)
- certain antidepressants such as fluoxetine (monoamine-oxidase inhibitors),
- certain medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole, fluconazole,
- fenfluramine ‹medicines that suppress appetite),
- ranitidine and cimetidine (medicines used to treat heartburn),
- fibrates (such as clofibrate) used to treat high cholesterol,
- insulin and other oral antidiabetic medicines (such as acarbose, metformin, thiazolidinediones, GLP-1 receptor inhibitors),

- certain medicines used to treat pain and inflammation (NSAIDs and salicylates),
- beta-blockers (used to control heart rhythm, treat angina, and reduce high blood pressure) may increase the chance that high or low blood sugar can occur. Also, they can hide the symptoms of low blood sugar.

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken with GLYGARD:

- danazol used to treat breast disorders, heavy menstrual bleeding and endometriosis is not recommended for use with GLYGARD. If it cannot be avoided, regular urine and blood glucose monitoring must be done. Your dose of GLYGARD may need to be adjusted,
- epinephrine (adrenaline), asthma medicines (salbutamol, terbutaline), cough and cold medicines containing ephedrine and pseudoephedrine,
- corticosteroids (cortisone-like medicines used to treat inflammation),
- calcium channel blockers, clonidine, diazoxide (cardiovascular medicines used to treat heart problems),
- chlorpromazine (tranquiliser or sedative also used for nausea or vomiting),
- lithium (used to treat certain types of depression),
- thiazide diuretics (water tablets),
- anti-epileptic medication such as phenytoin,
- glucagon (a hormone that assists with the breakdown of glycogen to glucose),
- female hormones oestrogen and progesterone,
- antibacterial medicines rifampicin and isoniazid,
- thyroid hormones,
- glucocorticoids (used to assist the body to break down carbohydrates, proteins and fats),

- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline).

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than GLYGARD, especially in elderly patients.

GLYGARD may increase the effects of anticoagulants (medicines which reduce blood clotting e.g. warfarin). Your dose of anticoagulant may need to be adjusted.

GLYGARD with food, drink and alcohol

GLYGARD must be taken with food or 30 minutes before a meal. The tablet be taken immediately before a substantial breakfast or the first main meal of the day. You should not miss a meal after you have taken the tablets.

Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking GLYGARD.

Do not use GLYGARD if you are pregnant or breastfeeding your baby (see **Do not take GLYGARD**).

Driving and using machines

Alertness and reactions may be impaired by hypo- or hyperglycaemia, especially when initiating treatment or altering doses. You should be aware of the symptoms of hypoglycaemia (low blood sugar) which include dizziness, poor concentration, confusion, sleepiness and blurred vision.

It is not always possible to predict to what extent GLYGARD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GLYGARD affects them.

GLYGARD contains lactose monohydrate

GLYGARD contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take GLYGARD

Do not share medicines prescribed for you with any other person.

Always take GLYGARD exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Initial dose:	40 to 80 mg per day, taken in divided doses, at breakfast and at dinner.
Maximum dose:	320 mg per day, taken in divided doses, at breakfast and at dinner.
General dosage:	2 tablets per day taken with meals. Take 1 tablet with breakfast and one tablet with dinner.

Your doctor will tell you how long your treatment with GLYGARD will last.

Do not stop treatment early because high blood sugar symptoms will return.

If you have the impression that the effect of GLYGARD is too strong or too weak, tell your doctor or pharmacist.

If you take more GLYGARD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take GLYGARD

If you forget to take GLYGARD, take a dose as soon as you remember, then continue to take GLYGARD at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking GLYGARD

Stopping this medicine could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

4. Possible side effects

GLYGARD can have side effects.

Not all side effects reported for GLYGARD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GLYGARD, please consult your health care provider for advice.

If any of the following happens, stop taking GLYGARD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic

reaction to GLYGARD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- low blood sugar levels — hypoglycaemia (see **Take special care with GLYGARD** for the list of symptoms)
- liver failure (signs include yellow discolouration of the skin and eyes (jaundice) and pain in the upper right abdomen)
- kidney problems (passing more urine than is normal for you or more frequently).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- dizziness,
- drowsiness,
- constipation,
- diarrhoea,
- stomach pain or discomfort,
- stomach spasms,
- decreased or increased appetite,
- heartburn,
- bloating,

- flatulence (gas),
- weight gain,
- nausea,
- vomiting,
- changes in sense of taste (metallic taste).

Less frequent side effects:

- decrease in the number of cells in the blood,
- resulting in abnormal blood test results including anaemia,
- low sodium levels in the blood,
- anorexia,
- blurred vision, worsening eyesight,
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin).

The following side effects have been reported but the frequency for them to occur is not known:

- hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, blistering or peeling of the skin, thinning of the skin, pale skin, unusual bruising.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of GLYGARD.

5. How to store GLYGARD

Store at or below 30 °C, in a dry place.

Store all medicines out of reach of children.

Store in the original container.

Keep the container in the outer carton.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GLYGARD contains

The active substance is gliclazide 80 mg.

The other ingredients are croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose (Pharma grade), povidone (PVK K30), purified talc.

What GLYGARD looks like and contents of the pack

GLYGARD is a white, circular, flat, bevelled tablets with a break line on one side and plain on the other side.

GLYGARD is packed in an Alu foil-Alu film blister with 10 tablets, packed in 60's and 500's.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in

First authorisation: 07 August 2002

Latest renewal: Not applicable

Revision: 09 December 2025

Registration number(s)

34/21.2/0070

Namibia: NS2 06/21.2/0317

Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.

MS